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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,035	02/28/2002	Carl R. Simmons	35718/242990 (5718-198)	6779
29122	7590	04/20/2004	EXAMINER	
ALSTON & BIRD LLP PIONEER HI-BRED INTERNATIONAL, INC. BANK OF AMERICA PLAZA 101 SOUTH TYRON STREET, SUITE 4000 CHARLOTTE, NC 28280-4000			IBRAHIM, MEDINA AHMED	
			ART UNIT	PAPER NUMBER
			1638	
DATE MAILED: 04/20/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/090,035	SIMMONS, CARL R.	
	Examiner	Art Unit	
	Medina A Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 13-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 10/31/03 in reply to the Office action of 07/29/03 has been entered. Claims 1 and 3 have been amended. Claims 1-4 and 13-17 are pending and are under examination.

All previous objections and rejections not set forth below have been withdrawn. Upon further consideration, the rejection under 35 USC 101 has been withdrawn. However, the rejection under 112, 1st paragraph of the claims as being nonenabling is maintained.

The Examiner will address only the arguments from the response to the prior art Office action that are relevant to the rejections contained in this Office action.

Claim Rejections - 35 USC § 112, 1st paragraph

Claims 1-4 and 13-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant's arguments filed 10/31/03 regarding the enablement of these claims have been considered but are not deemed persuasive.

The claims are drawn to isolated polynucleotides comprising SEQ ID NO:1, 3, 5, 7 and 9 and polynucleotide sequences having at least 80% sequence identity to SEQ ID

NO:1 and encoding a maize AFP1 protein. Applicant also claims a recombinant expression cassette, a vector, and a host cell comprising said nucleotide sequences.

Applicant argues that the claimed nucleotide sequences encode defense inducible proteins, based on the assertion that the sequences have been isolated from tissue resistant to fungal pathogen or treated with jasmonic acid. Applicant asserts that defense inducible proteins need not possess direct anti-pathogen activity. Applicant cites Xiong et al (2001) and Walton (Biochemical Plant Pathology, Plant Biochemistry, 1997, pp. 496-502) to support this assertion. (Response, pp 9-13).

These arguments are not persuasive because neither the instant specification nor Applicant's response provide evidence that shows the claimed nucleotide sequences have the function of encoding defense inducible proteins, and that it can be used for the production of transgenic plants with enhanced pathogen resistance. While all "defense inducible proteins" may need not possess direct antipathogenic activity, the claimed invention is directed to nucleotide sequences encoding a maize AFP1 protein sequences rather than a "defense inducible proteins". AFP1 protein encoding sequences are well known antifungal/antimicrobial protein, which has been isolated and characterized from various plant species (see Broekaert et al (US 5, 538,525) Attenborough (US 5, 861, 480). AFP1 proteins are known to possess direct antifungal/antimicrobial activity. No similarity is noted between the AFP1 proteins of the prior art and Applicant's SEQ ID NO: 2, 4, 6, 8, or 10, as stated in the last Office action.

Applicant also argues that the working examples disclosed in the specification supports the defense inducible activity of the claimed sequences. However, the only

working example disclosed in the specification does neither support direct nor indirect antipathogenic activity by the claimed sequences. In Example 3 of the specification, analyses of the antifungal or antimicrobial activity of the claimed sequences failed to show any antimicrobial activity. The specification discusses the analysis as follows, "there may be problems relating to pathogen specificity of the proteins or the proteins may be indirectly antimicrobial. Screening additional fungal or microbial pathogens could reveal direct antifungal or antimicrobial activity, while a transgenic plant constitutively expressing the AFPI gene can demonstrate indirect antifungal and antimicrobial activity". Applicant, however, has provided no guidance with respect to how to identify proteins, which may be indirectly antimicrobial. Therefore, it is apparent that further research considered undue is required before one skilled in the art would know how to use SEQ ID NO: 1, 3, 5, 7 or 9.

Applicant criticizes the criteria of identifying pathogen inducible proteins described in Van Loon reference as not being widely acceptable. However, Applicant has provided no scientific evidence to support this conclusion. With respect to Xiong et al (2001) and Walton (1997), copies of these references have not been provided, so they cannot be given any weight.

See *Genentech Inc v. Novo Nordisk A/S* 42 USPQ2d 1001, 1005 (Fed. Cir. 1997). The CAFC stated, "(P)atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable....While every aspect of generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be

provided in order to enable members of the public to understand and carry out the invention...".

Therefore, for the reasons given above and in the last Office action, the rejection is maintained.

Applicant is invited to provide evidence in the form of data or 1.132 declarations to support the AFP1 activity of the disclosed sequences.

Written Description

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office of 07/29/03. Applicant's arguments filed 10/31/03 have been fully considered but are not deemed persuasive.

As stated in the last Office action, Applicant has not described a polynucleotide having at least 80% sequence identity to SEQ ID NO: 1 and that encodes a maize AFP1 protein. While SEQ ID NO: 3, 5, 7, and 9 meet the claimed structural limitation, no antifungal or other antimicrobial function has been established for any of the disclosed sequences. Therefore, a mere recitation of a functional limitation in the claims would not provide adequate written description for the claimed invention.

Applicant is invited to provide evidence in the form of data or 1.132 declarations to support the AFP1 activity of the disclosed sequences.

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Remarks

Claims 1-4 and 13-17 are free of the prior art of record because the prior art does not teach or suggest isolated nucleic acids comprising the polynucleotide sequence of SEQ ID NO: 1, 3, 5, 7, 9, and a polynucleotide having at least 80% sequence identity to SEQ ID NO: 1 that encodes a maize AFP1 protein.

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and After final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

4/16/04

Mai

A handwritten signature in black ink, reading "Medina A. Ibrahim". The signature is written in a cursive style with a long horizontal line extending from the end.